

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY)	
AVERAGE WHOLESALE PRICE)	MDL No. 1456
LITIGATION)	
)	Civil Action No.
)	01-CV-12257-PBS
THIS DOCUMENT RELATES TO)	
)	Judge Patti B. Saris
<i>State of Montana v. Abbott Labs. Inc., et al.,</i>)	
02-CV-12084-PBS)	AFFIDAVIT OF
)	THOMAS HELD
<i>State of Nevada v. American Home Prods.</i>)	
<i>Corp., et al.,</i>)	
D. Nev. Cause No. CV-N-02-0202-ECR)	

STATE OF NEW JERSEY

ss.:

COUNTY OF MORRIS

THOMAS HELD, being duly sworn, deposes and says:

1. I am Global Head, Strategic Capabilities, in the Oncology Business Unit of Novartis Pharmaceuticals Corporation ("NPC"), a defendant in the above-referenced actions. I served as brand director of the NPC pharmaceutical drug Aredia from 1998 to 2002. I submit this affidavit in support of NPC's motions for summary judgment in *State of Montana v. Abbott Laboratories* and *State of Nevada v. American Home Products*. In particular, I explain below that Aredia, one of the NPC drugs at issue in these litigations, had no competition from non-NPC drugs throughout almost the entire relevant period of these litigations and that by the time Aredia did face competition from a non-NPC drug, NPC had ceased actively marketing Aredia.

2. I have personal knowledge or have made inquiries with respect to the facts set forth in this affidavit. I would be competent to testify with regard to the facts stated in this affidavit if called upon to do so.

3. I understand that one of the NPC drugs at issue in these litigations is Aredia (pamidronate disodium for injection). The National Drug Codes for the versions of Aredia at issue in these litigations are 00083-2601-04 and 00083-2609-01. As brand director of Aredia from 1998 to 2002, my responsibilities included developing the marketing messages for this drug.

A. Background of Aredia

4. Aredia is a physician-administered pharmaceutical drug. This means that a physician prescribes the drug, and it is then administered by either a physician or another healthcare professional. Aredia is indicated for the treatment of: (i) hypercalcemia of malignancy, an elevated level of calcium in the blood; (ii) Paget's Disease, a condition that causes bones to grow larger and weaker than normal; and (iii) osteolytic bone metastases of breast cancer and (iv) osteolytic lesions of multiple myeloma, conditions that cause bones to break down and fracture.

B. Aredia had no competition from non-NPC drugs

5. Until July 2001, the only other drugs in Aredia's therapeutic classes were used sparingly and were almost always administered only if Aredia did not achieve the desired clinical effect on the patient. One such drug, gallium nitrate, is very difficult to administer because it requires continuous infusion over 24 hours for five consecutive days. The other such drug, etidronate, lacks the positive safety profile of Aredia. In July 2001, NPC received approval from the U.S. Food and Drug Administration ("FDA") to market a physician-administered drug called Zometa for the treatment of hypercalcemia of malignancy. In March 2002, NPC received approval from the FDA to also market Zometa for the treatment of multiple myeloma and bone metastases of solid tumors.

6. Once NPC introduced Zometa for sale in the United States in July 2001, it stopped actively promoting Aredia to doctors (although Aredia was and is still available for purchase).

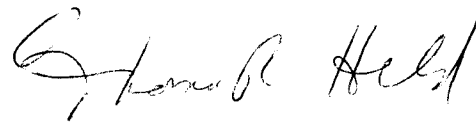
C. Generic version of Aredia

7. The generic version of Aredia (pamidronate disodium) was introduced for sale in the United States in December 2001 with approval from the FDA to be marketed for the same indications as Aredia.

D. NPC's marketing of Aredia

8. I understand that Plaintiffs have alleged that manufacturers have marketed the "spread" for certain drugs by communicating to doctors and/or pharmacists that they could earn more money prescribing and/or dispensing their drug than a competitor's drug. As set forth in ¶¶ 4-6 above, during the time that Aredia was actively promoted to physicians, it had no competitors in its therapeutic classes.

9. NPC never marketed Aredia based on the price that providers would be reimbursed by state Medicaid agencies or other third-party payors. NPC's marketing of Aredia focused solely on the drug's clinical efficacy and safety. NPC has a strictly-enforced policy that salespersons must not deviate from the approved message. If a salesperson deviated from the NPC-approved marketing message, they could be terminated.



Thomas Held

1-31-2007

Subscribed and sworn to before me

this 21st day of Jan, 2007

Sandra J. Carr
Notary Public

**SANDRA J. CARR
NOTARY PUBLIC OF NEW JERSEY
Commission Expires 2/23/2008**